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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/694,033	10/27/2003	David E. Berg	4425-PA1C2	3893

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MICHAEL WINFIELD GOLTRY
4000 N. CENTRAL AVENUE, SUITE 1220
PHOENIX, AZ 85012

EXAMINER	
FORD, ALLISON M	

ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 09/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/694,033	BERG ET AL.	
	Examiner	Art Unit	
	Allison M. Ford	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *70-87* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *70-87* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 70-87 are pending in the current application, all of which have been considered on the merits.

Priority

Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 120 is acknowledged. However, the fist paragraph of the instant specification must be amended to reflect the current status as a continuation of application 09/637,808, which further claims priority to provisional application 60/148,799.

Duplicate Claim Warning

Claims 77 and dependent claims 78-83 are substantial duplicates of claims 70 and dependent claims 71-76. Claim 84 is a substantial duplicate of claims 74 and 81. Claim 86 is a substantial duplicate of claims 76 and 83.

Applicant is advised that should any of the above mentioned claims be found allowable, the duplicate claims will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 70-87 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Initially it is noted that all the independent claims are directed to methods for diagnosing a blood sample; however, a blood sample is not actually 'diagnosed', a disease or disorder is diagnosed, the blood sample is merely tested.

Claim 71 references the method of claim 1 in the 3rd line, it appears it should refer to the method of claim 70, examination has been conducted as such.

In claim 77 there is insufficient antecedent basis for the limitation "the different quantitative blood tests" in the 3rd step of the method.

Claim 78 references the method of claim 8 in the 3rd line, it appears it should refer to the method of claim 77, examination has been conducted as such.

Claim 85 references the method of claim 15 in the 3rd line, it appears it should refer to the method of claim 84, examination has been conducted as such.

Claim 87 references the method of claim 17 in the 3rd line, it appears it should refer to the method of claim 86, examination has been conducted as such.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 70-72, 74-79 and 81-87 are rejected under 35 U.S.C. 102(b) as being anticipated by Wintrobe et al (Clinical Hematology, 1974).

Wintrobe et al disclose standard laboratory blood tests for evaluating hematostasis and blood coagulation. Among the various tests disclosed, Wintrobe et al teach (i) Tests of Specific Platelet Functions, including platelet adhesiveness by the in vivo method of Borchgrevink (See Pg. 1053) and platelet aggregation, measured by aggregometers (See Pg. 1054), wherein each of platelet adhesiveness and platelet aggregation are considered measures of platelet activation; (ii) Assay of Plasma Fibrinogen by measuring the quantity of fibrin (See Pg. 1060); and (iii) Analysis of fibrin-fibrinogen degradation products, including unpolymerized fibrin monomers (soluble fibrin monomers) by the ethanol gelatin test or by protamine gelation techniques (See Pg. 1061). Wintrobe et al further identify various coagulation disorders characterized by various levels of the different coagulation factors (See, e.g. Table 33-3, Pg. 1063).

Thus, Wintrobe et al teach diagnostic methods involving identification of conditions related to abnormal coagulation response in blood, including low levels of coagulation response, and instructions for performing and interpreting various quantitative blood tests in order to assist in diagnosing blood disorders (Claims 70-72, 74-79, 81-87). Therefore the reference anticipates the claimed subject matter.

Claims 70-87 are rejected under 35 U.S.C. 102(b) as being anticipated by Sorensen et al (Thromb Res, 1992).

Sorensen et al teach testing blood samples following trauma and surgery for abnormal coagulation and/or fibrinolysis response, comprising providing blood samples from multiple patients at day 0 (day of injury) and one day post-admission (day 1), assaying each of the blood samples for (i) prothrombin fragment 1 and 2, (ii) thrombin/antithrombin III complex, (iii) fibrin monomers, (iv) fibrin degradation products, and (v) fibrinogen degradation products (See Pg. 480). The blood test results revealed the levels of prothrombin fragment 1 and 2, thrombin/antithrombin, fibrin degradation products, and fibrinogen degradation products were significantly lower 1 day post-admission than at day 0 (See Pg.

481); thus Sorensen et al concluded haemostatic activation is a basic response to the injury, and rest after the injury causes a reduction in the coagulation response level (See Pg. 484) (Claims 70-87). Therefore the reference anticipates the claimed subject matter.

Claims 70-87 are rejected under 35 U.S.C. 102(b) as being anticipated by Dati et al (Seminars in Thrombosis and Hematosis, 1998).

Dati et al teach pregnancy can result in activation of hemostasis, in order to properly monitor the condition they suggest monitoring markers of hemostasis activation, specifically, thrombin-antithrombin III complex, antithrombin III itself, prothrombin fragment 1+2, soluble fibrin monomer, d-dimer, fibrinogen levels and platelet counts (See abstract). Dati et al has further identified and characterized several coagulation disorders associated with abnormal levels of each of the hemostatis activation markers (See Table 2); thus, by monitoring the level of each marker via routine blood tests (also disclosed in Table 2), one can correlate any abnormal levels to the appropriate disorder (claims 70-87). Therefore the reference anticipates the claimed subject matter.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 70-87 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 45-63 of copending Application No. 10/915,018. The two sets of claims are not identical, but are related as a genus-species, wherein the claims of the copending application only recite "a coagulation condition", whereas the instant claims require the condition to be "a low coagulation response", otherwise the methods are identical in that they require identification of the specific conditions, obtaining and testing one or many blood samples for thrombin fragments 1+2, thrombin/antithrombin complex, fibrinogen, platelet activation and/or soluble fibrin monomers, and if at least two of the test results are abnormal, using the results to assist in diagnosis of the condition. Thus, because the instant claims recite a specific coagulation condition (low activation response) they anticipate the copending claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Allison M. Ford whose telephone number is 571-272-2936. The examiner can normally be reached on 7:30-5 M-Th, alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Leon B Lankford, Jr
Primary Examiner
Art Unit 1651